



January 14, 2009

Re: FDA Docket FDA-2008-N-0429: Food Labeling; Current Trends in the Use of Allergen Advisory Labeling: Its Use, Effectiveness, and Consumer Perception; Public Hearing; Request for Comments

I am submitting public comment on behalf of Kids With Food Allergies (KFA), a nationwide nonprofit support organization founded in 2005 and currently serving more than 14,000 members, most of whom are parents raising children with food allergies. KFA's mission is dedicated to fostering optimal health, nutrition, and well-being of children with food allergies by providing education and a caring support community for their families and caregivers. I am also the parent of an 18 year-old son with lifelong food allergies who's had a number of anaphylactic reactions to foods, at least one of which was due to cross contamination that I did report to the FDA back in 2003. The issue of cross contamination is a serious one and on behalf of KFA, I thank the FDA for requesting public comment to help develop its strategy to improve labeling to better serve consumers.

More than 3 million children in the United States have food allergy to one or more of the 8 major allergens: milk, eggs, soy, wheat, peanut, tree nut, fish and crustacean shellfish. Food allergy can be serious and sometimes fatal. Since there is no cure for food allergy, the only way to manage a food allergy is through avoidance of the food(s) to which a child is allergic and prompt treatment with injectable epinephrine should a reaction occur. It is for this reason that label reading and choosing safe foods are of utmost importance for keeping a child with food allergies reaction-free.

As an organization that provides education and peer support on a grass-roots level, we are in close contact with our members who are passionate and vigilant about buying safe products and reading labels to keep their children safe and well-nourished.

Our member-parents share information with us about problems they've had with food labels. They also tell us their often heart-wrenching stories when their children have allergic reactions to foods that the parents thought were safe but after investigation, the products were found to have issues with cross contamination. Often it is due to the fact that parents have the misconception that allergen advisory labeling is mandatory when in fact, it is not. They are lulled into thinking a product is safe because they don't see an allergen advisory statement advising them that the product 'may contain' an allergen they need to avoid. They are not fully aware of the fact that as consumers, the burden is on them to contact manufacturers to make sure a product does not have any cross contamination issues of concern for the food allergies they manage, especially when a voluntary allergen advisory statement is not present.



KFA is providing comment on some of the issues and questions for discussion. To help formulate a comment, KFA conducted a survey in November 2008 among its members regarding allergen advisory statements. 455 individuals responded to the survey; 98.7% were parents of children with food allergies. Attached to this comment is Appendix A, which contains a list of personal comments and stories to provide further insight into the frustrations and challenges parents have in reading labels and finding safe foods for their children.

### **Issue 2, Question 8**

*What specific advisory statements adequately inform consumers of the potential risk of cross contact with allergenic materials? What advisory statements most accurately communicate to consumers and their caregivers the potential risk of the presence of allergens. Why?*

The current practice of voluntary advisory statements is confusing at best, is dangerous at its worst, and has resulted in reactions reported to us by our members. Just this week we heard from a member whose child suffered anaphylaxis due to cross contamination in a food without an advisory statement. As a parent of a child with a life-threatening food allergy, even I've had my son land in the emergency room with anaphylaxis due to cross contamination in a food product without an advisory statement.

In addition, the variations in wording and in where voluntary allergen advisory statements are located on packaging are also sources of confusion and need to be improved. Mandatory allergen advisory labeling in a consistent location on the packaging, that uniformly and intuitively conveys risk to an allergic consumer is needed. From our survey:

- 99.8% responded that advisory statements should be mandatory for the 8 major allergens.
- 89.6% responded that a consistent location to find an advisory statement on a package would be somewhat or very helpful.

### **Issue 2, Question 10**

*In addition to the information and data mentioned in this document, what additional information or data are available to assist us in understanding consumer perceptions of, use of, and the need for specific advisory statements and advisory labeling in general?*

The use of dedicated equipment "free of" specific food allergens is very helpful information to those of us searching for safe foods for our children. If allergen advisory labeling included this type of information, it would help shoppers choose products they can use for their children. Many parents, myself included, will just put a product back on the shelf if in doubt rather than take the time to contact manufacturers and quiz them on their manufacturing practices to make a decision about a product if the label is unclear. Dedicated equipment information on product



labeling would provide information to help consumers decide to purchase a product rather than putting it back on the shelf.

From our survey:

- 93.7% responded that dedicated equipment statements should be mandatory for products that are made on dedicated equipment “free of” any of the 8 major allergens (milk, soy, eggs, wheat, peanuts, tree nuts, fish, shellfish).

### **Issue 3, Question 11**

*What elements are needed in an advisory statement to adequately inform consumers of the potential for the inadvertent presence of an allergen and would communicate to allergic consumers a consistent and effective message regarding the risk of consuming the product?*

From our survey:

- 83.4% responded that a clear and consistent title for an allergen advisory statement such as “Allergy Information:” (for example, “Allergy Information: may contain peanuts,” or “Allergy Information: not safe for peanut allergy”) would be somewhat or very helpful.
- 88.2% responded that including any dedicated equipment information within the allergen advisory statement on a package that clearly specifies which of the 8 major allergens the product is “free of” (for instance: “made on dedicated equipment free of milk, soy, eggs.”) would be somewhat or very helpful.
- 76.3% responded that a statement such as “not safe for those with peanut allergy” rather than a statement such as “may contain peanut.” would be somewhat or very helpful.
- 89.5% responded that including any manufacturer contact information within the allergen advisory statement on a package to find out more information about the company’s allergen control measures would be somewhat or very helpful.

### **Final Comments**

The allergen advisory statements that are ultimately chosen by the FDA need to be simple, clear and intuitive, and take into consideration the fact that individuals other than the child or his parents often have to read labels to determine whether a food is safe for an allergic individual (teachers, caregivers, food service workers, hospitals, etc.) These individuals may not be skilled label readers and the potential for error is increased in the absence of something simple, clear and intuitive.

The advisory labeling also needs to factor in the varying levels of literacy and increasing numbers of individuals for whom English is not their primary language. With that in mind, symbols or graphics might be a more helpful alternative than carefully worded statements.



Although KFA would fully support a public health awareness campaign for allergen advisory labeling improvements, a campaign should not be done in lieu of having a clear, simple and intuitive way to convey any allergen advisory statement on products.

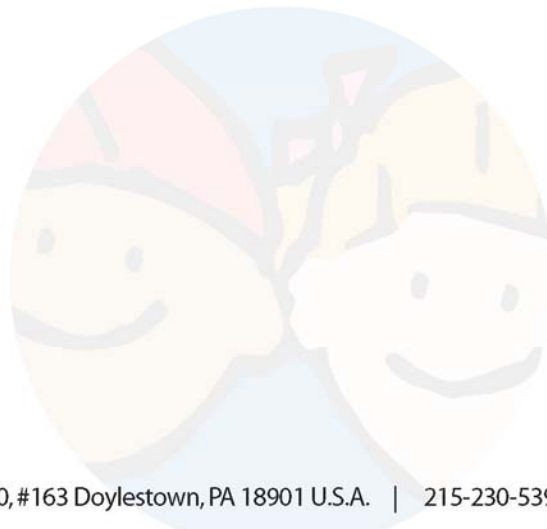
Evaluating consumer understanding of the meaning of any new allergen advisory statements should be an essential part of the process of deciding upon which statements are ultimately put into effect.

Thank you for this opportunity to submit a public comment on this important issue that needs to be addressed promptly. Please let me know if there is some way KFA can be assistance to the FDA in this allergen advisory labeling effort.

Sincerely,

A handwritten signature in purple ink that reads "Lynda Mitchell". The script is cursive and fluid.

Lynda Mitchell  
President





## Appendix A.

The following are comments from some of those who completed our survey that provide personal insights into the frustrations and challenges parents have in reading labels and finding safe foods for their children. Some are unrelated to the allergen advisory labeling issue specifically, but they are also included to show the range of concerns that families face.

1. Accurate labeling is really imperative to the health and safety of our children. A recall of a food product after our children have already been to the Emergency Room is TOO LATE!
2. I want to scream at these companies that are so irresponsible to their consumers and seem to not care!!! They just want to make money.
3. Manufacturers need to take responsibility in proper labeling so we are not playing roulette with our children's' lives. To live in constant fear that a label is not accurately listing allergens, is a hard way for parents to live.
4. My family has completely switched groceries for my daughter's allergies so she is safe and doesn't feel different or left out. We have had to give up a lot of products just because I don't know for sure if their equipment also makes gluten, egg, milk, or peanut products.
5. I also would love to see companies held accountable for their products living up to their statements!
6. When companies realize the size of the food-allergic market, dedicated equipment notices should be clearly an advantage to them so hopefully, they would want to include them rather than have to be required.
7. I would love the companies to "step up to the plate" in regards to this issue. I think this should be just as important-if not more so-than the nutritional information on packages. Our children's LIVES are at stake!
8. My son is allergic to soy, egg, peanut and tree nuts. I often buy things that are made in "a facility that processes" and hope for the best. So far we have been lucky but a lot a time I leave the grocery store in tears because it is so overwhelming. I would never want to intentionally harm my child. I am a very logical person and understand the cost of mfg., but to put my child's life at risk because of inconsistent wording is too much.





9. I have two sons ages 5 and 4 that have a peanut allergy. I understand more than others how to read a food label after a lot of research. Even then I can be confused at times. Imagine sending your child to a friend's house that doesn't have to read labels and haven't learned.
10. Our main concern is finding the allergy information in a consistent place. Depending on the severity of my son's allergies we decide ourselves if he can eat something processed on equipment that also processes an allergen. I would find it a waste not to inform people if something was processed on allergen free machines.
11. The labels need to be spelled out for children. There is going to be a day when my son is going to read the labels and have to decide for himself. I want the wording to be less confusing so he is clear about its safety. "May contain" is very different than "is not safe to eat". Children won't be tempted by the wording trace of or may contain etc.
12. It amazes me that a potentially "deadly" ingredient to a human would not be required/regulated as far as labeling. Isn't it the job of the "producer" to protect the consumer from potentially hazardous ingredients?
13. It really wouldn't take that much to add these things and we are talking about the safety and lives of babies! It isn't a concern of course until it is your child who is affected. It would be such a help to families with children afflicted with severe food allergies!
14. More stringent regulations and enforcement are **ESSENTIAL** to our very survival. This has been taken too lightly in the past.
15. This is serious; we need to make the ingredients and potential cross contamination ingredients known to consumers. It needs to be clear for all to see and read. No questions after reading the statements. Our young children need to be able to easily find this information for their safety. The schools, friends, and family members that are not used to reading labels need to clearly see what they are looking for. So our children can lead as close to a normal life as they can and not have to miss out on so much because we don't know if something is okay. Also the schools need to be held more responsible during lunch to ensure our children's safety! Not make it too difficult for the parent and child... making the child bring a lunch instead of enjoying school lunches like their friends.
16. We need to have accurate labels for the ingredients, and processing and packaging aids. There are too many allergens that are hidden in foods and food products, with nothing on the label to warn people that their allergens are contained in the product. Corn is a major offender, and corn allergy is totally ignored, and not labeled at all, in most cases.



17. All ingredients should be listed clearly on each label. Food should be listed as being altered by Genetic Modification, irradiation just as pasteurization is labeled. Human health is more important than the company's secret formula
18. I also have a small child who has FPIES to Rice Protein. Which rice is not a major allergen. However, the labeling will say "Modified Food Starch". Well, I have to call the company and wait several days for a response if they even call me back, to inform me which Flour they used. This is ridiculous! There are people allergic to Corn, Wheat, Rice, etc... They need to specify "Wheat Flour, etc". So many food products in the supermarket contain "Modified Food Starch"!
19. My 11 year old son is severely allergic to peanuts. I don't give him anything that is a "may contain" or a "processed on/in". This definitely needs to be mandatory on packaging. It is exhausting to call all of these companies repeatedly to find out if something falls into those categories or if their practices have changed.
20. It would be most helpful if the information on the labels was as accurate as possible. I'm hearing of foods that have hidden ingredients. It is difficult to decide if the label is not accurate.
21. Don't want companies to label everything as not safe because it is easier and thereby eliminating potentially safe foods
22. It is hard to teach my 5 year old peanut allergic child how to read labels when they are inconsistent, vague and confusing. For example, McDonalds has posted "may contain peanuts" for their snickers shake. It is a certainty that the shake contains peanuts. On the other hand, a responsible manufacturer lists "may contain peanuts" when peanuts are present in the factory yet extensive measures are undertaken to prevent cross contamination, and this product is likely peanut free. Given this uncertainty in labeling...what do I teach my child about reading labels and determining the safety of food?
23. I wish that the allergy warnings would be in bright colors.
24. Manufacturers slapping some sort of "may contain" warning on almost everything has made the situation worse. It has increased consumer anxiety.
25. Our children can have major health problems if they ingest these foods. We purchase them under the guise that they are safe and then we read articles about children having allergic reactions. Please help keep our children safe!



26. I would like to see labeling for sesame and other seeds.
27. It is such an inconvenience to have to call companies on a weekly basis, speak with uneducated personnel who read from a script, be told they will call you back and they don't, have to really dig to get answers - it is draining and time consuming... Website information should be made more easily accessible and updated as needed. It should not be so hard to find this information out.
28. As a parent of a food-allergic child, my spouse and I have a good understanding of safe foods, where to look for allergy information and what various labeling statements make a certain food either safe or unsafe. It's difficult, however, to explain to relatives, caregivers, etc. what is safe and what isn't when statements, locations and manufacturers' practices all vary. Consistency would definitely help us to educate those people involved in the care of my child.
29. I shop for snacks for a school with severely allergic kids... it took me about half a year to call all the companies, check out their technical manufacturing processes, and to get responses from them. On some boxes there was no information at all who to contact. I googled, searched.... and it took a lot of research. Having cross-contamination labeled would make such a difference for people with allergies and increase the quality of life, but it would also increase the quality of life of all the kids in the school as the kids are all limited by the things the children with allergies can have. Labeling will make things easier for administrators, teachers, children, restaurant owners, and less stress means more energy and time for everyone else.
30. Sesame, the 9th most common allergen must be addressed!
31. It has been very difficult adjusting to food allergies but there is so much more to be done in regards to regulating ALL products whether it is food at home, food in restaurants, or non food products. It is all about keeping our kids and loved ones safe!
32. "Not safe for peanut allergies" does not seem clearer to me than "may contain peanuts" especially with x-contamination where some can tolerate and some can't. It also seems redundant if there is a clear mandatory allergens label in place. I prefer the manufactured on shared equipment with ... or manufactured on dedicated lines in a facility that also processes ... I do not use "may contain" products, but have friends who are comfortable doing so. Knowing the source of x-contamination in those cases would be valuable. Another thing that would be HUGELY valuable is if companies had to disclose if there were top 8 allergens in their less than 2 percent, natural and artificial flavors gray areas. Dealing with many non-top 8 I would truly appreciate total clarity in labeling but that will not happen with all the proprietary recipes etc.





33. The terms "spices," "natural flavorings," and "artificial flavorings" are frustrating. Though spice allergies are rare, they exist. My daughter has a cinnamon allergy. It is difficult, if not nearly impossible, to determine what spices are in some foods. Manufacturers often do not know because they are shipped in from elsewhere or the information is "proprietary." Manufacturers should be required to list specific information in the ingredient list.
34. More and more children and adults have serious food allergies. This is a public service that has long been needed and is clearly overdue.
35. I've read articles stating that companies have listed items as gluten-free when in fact it contained gluten. Companies should be regulated about their FREE OF statements as well to ensure that the product truly is safe when it says it is.
36. Not only food items can cause reactions in people my son has a soy, oatmeal, and almond allergy and has had reactions to lotions and soaps that have any one of these in them. We try to read everything carefully but sometimes the terminology is not clearly understandable. I am not a chemist so I do not at times catch the usage of some words without the use of research. Why can't just plain language be used?
37. The way it is now, sometimes even I miss the "may contain" statement. I need to teach my children how to read a label so they can keep themselves safe as they get older. Having all of the allergen information in a consistent place on the label, every time, every company, will make it that much easier for all food-allergic people. It should be a no-brainer --- you sell a food product, you should put a clear, concise, consistent label on that product, every time for every product.
38. The FDA needs to understand that these labels can literally be a matter of life or death for some people; and proper labeling vastly improves the quality of life for all families with food allergies. Cross-contamination is also a major issue to me; it is so frustrating and frightening, constantly having to worry about undeclared cross-contamination
39. Don't forget about sesame :) .
40. The danger of cross-contamination is like playing Russian-roulette with my child's life.
41. I'd love to see the labeling laws expanded to include non-top 8 allergens. My 2 year old son is severely allergic to sesame which is labeled as an allergen in Canada and the EU but not the U.S.



42. I wonder why, when so many lives are at stake, regulations are not mandatory and more stringent. Especially with children who are in the care of several different people throughout the day - teachers, daycare providers, grandparents, etc. - consistent labeling would reduce anxiety in parents and increase confidence in care providers that the children are cared for properly. Too often, food allergies are taken with a nonchalant attitude. People seem to equate food allergies with seasonal or environmental allergies that are typically not life-threatening.
43. I take responsibility for my 3 year old's allergies, and when he is old enough, he will. We don't ask for an allergen free world. We only ask for a way that we can be sure what we're eating is safe. Changing a label can save lives!
44. If allergen statements could be included on medications and things like toothpaste, this would also be extremely helpful.
45. Again, we are requesting that you please require ALL food companies to have clear allergen warnings on their products!!! Please!!! It would be so helpful to all of us! As parents we know specific terms to look for that contain the allergens our son can not have, but having a clear warning would be helpful not only to us but also to school staff and other caregivers who are not familiar with all the "hidden" terms. Please highly consider making a mandatory requirement for all foods to be clearly labeled with allergens!
46. I am so thankful that the government is finally looking at this, and I hope and pray that they can take steps to make label reading safe for people with life threatening food allergies. My son is allergic to peanut and tree nut, so applying this to the top 8 allergies would help us a lot. Having contact information for people with allergies other than the top 8, and making sure that manufacturers have a clear allergy policy would help people with allergies other than the top 8. It is maddening to call a company like Con Agra, and be told that any product can contain any allergen. I don't think companies should be allowed to do this. Either they know what's in their foods, or they shouldn't be allowed to sell it in the U.S. I also have concerns about imported foods, so if something is sold in the U.S., but made in Mexico, it is difficult to tell from the label if we can trust it or not, it would be great if this could be clearer for us. Of course, we always want more (especially for our children), so bakeries that provide labels for baked goods are often missing any allergen warnings, so it would be great if they could be included in some of this also, as these are the products that are most often brought to school functions/parties/events. While I'm on my soap box, how about public venues, such as baseball parks, that sell food. Could they have some type of ingredient information available, and of course the final challenge would be restaurants, safe dining.....do we dare to dream?



47. Make corn one of the top allergens and require labeling as such.
48. It is tough enough to raise child w/food allergies. We shouldn't have to take a gamble w/the food we provide to them. We need more accurate information.
49. Stories about children having reactions to products that should be safe make me want to stay in my house and make everything from scratch. If the manufacturers want our food dollars, they need to go much further to ensure our foods are not contaminated. These are poisons to allergic individuals!
50. This affects so many children I can't believe that it is addressed so casually, both by manufacturers and our government.
51. My 8 yr old daughter has life threatening food allergies to all of the 8 allergens and then some, this is not something to be taken lightly, I will really like to see something done about this for my daughter came close to death 3 times due to cross contamination.
52. Nitpicking about the verbiage seems to put heavier burdens on the manufacturers. If they cannot handle the new guidelines, I fear that everything will contain the "made in a facility..." disclaimer rather than really getting to the issue of cross contamination safety. I appreciate the strides made on labeling in the last 5 years, but debating the wording is pointless, all the aforementioned choices in this survey on wording of possible contamination issues, read the same way to me. No way you mentioned was "stronger" to me than another, if it mentions my kid's allergens, we don't eat it, period
53. One fear I have about mandating some labeling is that companies will choose the easiest way out, e.g., stating their product is not safe for people with any food allergies. This could reduce the number of products we could feed our severely food allergic child. I hope they can see that with so many food allergic people now that it is in their best interest to be clear and honest in their labeling practices.
54. This is a life and death issue. As our children are left in the hands of teachers and child care workers, and cafeteria staff, the risk becomes exponential. Advisory labeling is fundamental to the safety of our children with allergies.
55. As a 7 year veteran of reading labels, anytime you can make my job easier, it will be better. I also think making it easier for those who may be new or perhaps unfamiliar with food labels would be helpful...for example, the mother of non-allergic child who has my egg-allergic child over for a play date...it would give everyone a little peace of mind to know the labels are easy to understand. Knowledge is power.